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Please find below and/or attached an Office communication concerning this application or proceeding.

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/667,534
Filing Date: September 22, 2003
Appellant(s): RIOS, ADAN

Travis M. Wohlers (Reg. No. 57,423)
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 23 January, 2008, appealing from the Office action mailed 16 May, 2007.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of invention contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

No evidence is relied upon by the examiner in the rejection of the claims under appeal.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 40-50 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had **possession** of the claimed invention. *Univ. of Rochester v. G.D. Searle & Co., Inc.*, 358 F.3d 916, 920, 69 U.S.P.Q.2d 1886, (Fed. Cir. 2004). *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 296 F.3d 1316, 63 U.S.P.Q.2d 1609, (Fed. Cir. 2002). *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 43 U.S.P.Q.2d 1398, (Fed. Cir. 1997). *Fiers v. Revel Co.*, 984 F.2d 1164, 25 U.S.P.Q.2d 1601, (Fed. Cir. 1993). *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 18 U.S.P.Q.2d 1016, (Fed. Cir. 1991). *In re Rasmussen*, 650 F.2d 1212, 211 U.S.P.Q. 323 (C.C.P.A. 1981). *In re Wertheim*, 541 F.2d 257, 191 U.S.P.Q. 90 (C.C.P.A. 1976).

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., *Vas-Cath, Inc., v. Mahurkar*, 935 F.2d at 1563, 19 U.S.P.Q.2d at 1116. The issue raised in this application is whether the original application provides adequate support for the broadly claimed genus of inactivated reverse transcriptases

(RTs). An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997). The claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the biomolecule of interest. *In re Bell*, 991 F.2d 781, 26 U.S.P.Q.2d 1529 (Fed. Cir. 1993). *In re Deuel*, 51 F.3d 1552, 34 U.S.P.Q.2d 1210 (Fed. Cir. 1995). A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. See, e.g., *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 U.S.P.Q.2d 1895, 1905 (Fed. Cir. 1995). The court noted in this decision that a **"laundry list"** disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not reasonably lead those skilled in the art to any particular species.

An applicant may show possession of an invention by disclosure of drawings or structural chemical formulas that are sufficiently detailed to show that applicant was in possession

of the claimed invention as a whole. An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. For some biomolecules, examples of identifying characteristics include a nucleotide or amino acid sequence, chemical structure, binding affinity, binding specificity, and molecular weight. The written description requirement may be satisfied through disclosure of function and minimal structure when there is a well-established correlation between structure and function. Without such a correlation, the capability to recognize or understand the structure form the mere recitation of function and minimal structure is highly unlikely. In the latter case, disclosure of function alone is little more than a wish for possession; it does not satisfy the written description requirement. *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1566, 43 U.S.P.Q.2d 1398, 1404, 1406 (Fed. Cir. 1997), *cert. denied*, 523 U.S. 1089 (1998). *In re Wilder*, 736 F.2d 1516, 1521, 222 U.S.P.Q. 369, 372-3 (Fed. Cir. 1984). Factors to be considered in determining whether there is sufficient evidence of possession include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention.

The crux of the statutory requirement governing written description is whether one skilled in the art, familiar with the

practice of the art at the time of the filing date, could reasonably have found the later claimed invention in the specification as filed. *In re Kaslow*, 707 F.2d 1366, 1375, 217 U.S.P.Q. 1089, 1096 (Fed. Cir. 1983). *In re Wilder*, 736 F.2d 1516, 1520 222 U.S.P.Q. 349, 372 (Fed. Cir. 1984, *cert. denied*, 469 U.S. 1209 (1985). *Texas Instruments, Inc.* v. *International Trade Comm'n*, 871 F.2d 1054, 1063, 10 U.S.P.Q.2d 1257, 1263 (Fed. Cir. 1989). Moreover, the courts have stated that the evaluation of written description is highly fact-specific, and that broadly articulated rules are inappropriate. *In re Wertheim*, 541 F.2d 257, 263, 191 U.S.P.Q. 90, 97 (C.C.P.A. 1976). *In re Driscoll*, 562 F.2d 1245, 1250, 195 U.S.P.Q. 434, 438 (C.C.P.A. 1977). It is also important to remember that the true issue in question is not whether the specification enables one of ordinary skill in the art to make the later claimed invention, but whether or not the disclosure is sufficiently clear that those skilled in the art will conclude that the applicant made the invention having the specific claim limitations. *Martin* v. *Mayer*, 823 F2d 500, 505, 3 U.S.P.Q.2d 1333, 1337 (Fed. Cir. 1987).

The claims of the instant application are directed toward a method of eliciting an immune response by obtaining a viral particle comprising a reverse transcriptase (RT) that has been inactivated with one or more azido-labeled compounds followed by irradiation. The broadest claims are not directed toward any particular source of the RT enzyme. Perusal of the disclosure demonstrates that applicants were clearly focused on HIV-1, in particular for the development of an efficacious vaccine. In summarizing their invention (p. 2, lines 11-19), applicants stated the following:

> The present invention relates generally to the fields of virology, immunology, disease treatment, and prevention.

> More particularly, it concerns HIV particles with inactivated reverse transcriptase, methods of inactivation, and the use of such particles to prepare components of HIV and to elicit effective immunological responses to HIV. These immune responses are useful in producing diagnostic reagents, assays, and kits for the diagnosis of HIV and related retroviral disease, providing protection from an HIV challenge, and assisting an HIV-infected individual in controlling the replication of the virus. Methods of inactivation are useful for preventing disease through decreasing the risk of infection associated with exposure to HIV infected tissues and materials. [p. 2, l. 11-19]

The specification in describing the related art discusses only HIV. No other retroviruses are described to any extent. The interest in HIV RT was further manifest in the summary of the invention (bridging paragraph, pp. 10-11):

> The viral particles of the present invention mimic infectious HIV particles but do not cause infection (i.e., establishment of a perpetuation of HIV within the recipient host due to incorporation into the genome of cells within the host) and may be used as immunogens in a vaccine or in the development of effective treatments of HIV infection. Non-infectious HIV particles are useful not only in vaccination, but also in diagnosis, manipulation, and development of treatments for HIV infection. HIV particles rendered non-infective by photoinactivation may be used as an immunogen for making antibodies, or screening for antibody-like binding compounds that recognize and bind to native HIV particles. [bridging paragraph, pp. 10-11]

The summary of the invention continues from pages 10-15. Every reference is directed toward HIV inactivated viral particles. No other retroviruses or retroviral elements are even discussed. The specification discusses HIV biology and the worldwide geographic distribution of the virus (pp. 16-18). All of the examples provided in the specification involve HIV-1 RT (e.g.,

see Example 1: photoinactivation of HIV-1 RT [p. 30]; Example 2: inactivation of HIV particles and infected cells [p. 31]). Once again, there is no mention of any other retroviral or retrotransposon RTs.

The *Retroviridae* encompass several genera including the avian-leukosis-sarcoma viruses (e.g., Rous sarcoma virus (RSV), avian myeloblastosis virus (AMV), avian erythroblastosis virus (AEV), avian myelocytomatosis virus (MC)), mammalian C-type retroviruses (e.g., Moloney murine leukemia virus (Mo-MLV), Harvey murine sarcoma virus (Ha-MSV), Abelson murine leukemia virus (A-MuLV), feline leukemia virus (FeLV), reticuloendotheliosis virus (REV), spleen necrosis virus (SNV)), B-type viruses (e.g., Mouse mammary tumor virus (MMTV)), D-type viruses (e.g., Mason-Pfizer monkey virus (MPMV), "SAIDS" viruses), HTLV-BLV viruses (e.g., Human T-cell leukemia virus (HTLV-I and -II), Bovine leukemia virus (BLV)), lentiviruses (e.g., human immunodeficiency virus (HIV-1 and -2), simian immunodeficiency virus (SIV), feline immunodeficiency virus (FIV), bovine immunodeficiency virus (BIV), Visna/maedi virus, caprine arthritis-encephalitis virus (CAEV), equine infectious anemia virus (EIAV)), and spumaviruses (e.g., simian foamy virus (SFV), human foamy virus (HFV), human spumaretrovirus (HSRV)). The specification fails to discuss any other virus other than HIV. Once again, there is no indication that applicants contemplated inactivating RT from any of the aforementioned viruses except HIV-1.

The disclosure fails to teach the inactivation of any other retroviral or retrotransposon RTs other than HIV-1. Accordingly the skilled artisan would conclude that applicants were not in possession of the full genus claimed.

(10) Response to Argument

Applicants rely upon page 16 to assert that the disclosure provides support for the full breadth of the claimed invention. The passage relied upon contains nothing that would direct the skilled artisan to any particular retrovirus. Applicants further rely on page 3 of the disclosure and a series of exhibits to support their arguments. Page 3 simply notes that all retroviruses employ a reverse transcriptase (RT) to replicate. Once again, nothing in this portion of the specification would lead the skilled artisan to any particular retrovirus. The various exhibits relied upon also fail to support applicants' arguments. Exhibit 1 (Flavell, 1995) notes that several different retroelements employ reverse transcriptases (RT) for replication. This teaching does not disclose the genetic relatedness of the different RTs. Several types of retroelements are believed to utilize RTs including Group II introns, retrons, fungal mitochondrial plasmids, Non-LTR retrotransposons, LTR retrotransposons, hepadnaviruses, and caulimoviruses. Most of these elements are not genetically related. Concerning exhibit 2, Boeke (2007) simply discusses the origins of RT. Once again, nothing in this reference leads the skilled artisan to any particular species. Exhibit 3 (Nakamura *et al.*, 1997) simply asserts that telomerases are part of a group that encompasses retroelements. Once again, this reference does not disclose the preparation of other inactivated retroviruses. Exhibit 4 references a Springer and Britten (1993) publication. However, the authors simply performed a phylogenetic analysis of the *gypsy* group of LTR retrotransposons. There was no discussion of photoinactivation or the generation of vaccines. Lingner *et al.* (1997) (exhibit

5) simply reports that Telomerase has RT motifs. Valverde-Garduno (1998) and Seifarth *et al*. (2000) also fail to remedy the deficiencies of the specification. Finally, it was argued that numerous RT-binding compounds were present in the prior art. This argument also fails to cure the deficiencies of the disclosure. The issue is not whether or not the skilled artisan can make the claimed invention, but whether or not they were in possession of a sufficient number of embodiments to support the full claim breadth. Considering the teachings of the specification, the skilled artisan would reasonably conclude that applicants were not in possession of the claimed invention at the time of filing.

(11) Related Proceedings Appendix

No court or Board decisions were identified in the Related Appeals and Interferences section.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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13 April, 2008